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**Outline**  
**Statement of Robert G. Pinco and Mary L. Johnson**  
**Buchanan Ingersoll P.C.**

**OTC Part 15 Hearing: June 28, 2000**  
**Holiday Inn, Gaithersburg, MD**

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**I. History of OTC Review (R. Pinco)**

**A. 1970's – OTC Review Early Years**

- R. Pinco former Director of OTC Review and Executive Secretary of the Commissioner's steering committee for OTC drugs
- In the beginning, review of OTC drugs a high priority – determining status of over 400,000 products
- Goals:
  - (1) Perceived failure of litigation as a regulatory model (case by case enforcement not efficient)
  - (2) Legislative approach to regulating OTC drugs rather than adversarial;
  - (3) Moratorium instituted on regulatory actions against modifications to products that were changed to be consistent with safety and efficacy requirements of the review process
  - (4) Supported a healthy, innovative industry
- Legislative approach was successful (win-win situation)
  - (1) Building relationship between FDA and consumers, industry, scientists and other government agencies;
  - (2) Senior agency management directly involved in policy. Resulted in rapid change (e.g., zirconium);

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- (3) Industry gained respect because it did not resist regulation;
- (4) Stimulated innovation, scientific research, and improved quality of products;
- (5) Benefit to public health.

## **B. 1980's – OTC Review's Changing Focus**

- Loss in focus –

- (1) Phasing out of personnel instrumental in development of the OTC Review program;
- (2) Interest of senior management waning;
- (3) New breed of office directors with backgrounds in New Drug Review (e.g., “NDA way or the wrong way”);
- (4) Shift in interest of Office and Division Directors to Rx to OTC switches.

- Change perhaps due to a number of factors –

- (1) Generic drugs,
- (2) PDUFA,
- (3) Early success of OTC Review – perception that work was finished

## **II. Outstanding Concerns – Diminution of Agency Support (R. Pinco)**

- Limited staffing in OTC Review – Downsizing

- (1) Persons with institutional knowledge no longer present;
- (2) Limited resources (e.g., no user fees)

- Increased number of clearance levels for Federal Register publications (from 6-8 levels in the early 1970s to 40+ levels in the late 1990s)

- Agency delays in addressing industry petitions and completing rulemaking
  - (1) Sunscreen example – 20 year old petition
  - (2) Foreign marketing – 10 year old petition
  - (3) Frustrating to receive requests from FDA to withdraw pending petitions because information outdated.
  
- NDA model being used to regulate OTC drugs
  
- More adversarial than collaborative
  - (1) Experience of indifference of Agency at feedback meetings (e.g., sunscreens);
  - (2) Agency reticence regarding requests for meetings;
  - (3) Don't want to repeat dietary supplement mistake – FDA had an opportunity to regulate as drugs (e.g., Phytomedicine petition). FDA's unresponsiveness to interests of industry lead industry to abandon OTC process when DSHEA was adopted in 1994. Now dietary supplement market is \$21 billion industry.

### **III. Future Direction (R. Pinco and M. Johnson)**

#### **A. What is the purpose of the OTC Review and Division? (R. Pinco)**

- Statute distinguishes between “old drug” and “new drug” – Not a “one size fits all” (i.e., NDA) framework;
- OTC Review was not created by statute. FDA has regulatory flexibility if it wants to exercise it;

- OTC Review should be viewed as long-term mechanism for addressing regulation of all 400,000 OTC products rather than just “new drugs” (not just for Rx to OTC switches);
  - (1) Sunscreens – critical public health need; U.S. epidemic of sun-induced skin cancer.
  - (2) As a result of the sunscreen rulemaking, the number of available sunscreens was significantly reduced from ANPR stage to Final Rule stage. Meanwhile, there have been significant improvements in UVA sunscreen protection that are inaccessible to the U.S. public.

**B. How could the OTC review process be improved? (M. Johnson)**

- (1) Eligibility Criteria for the OTC Review (proposed “foreign marketing” rulemaking)
  - A significant step in the right direction (e.g., ICH world harmonization efforts).
  - However, as noted in industry comments proposed standards should be commensurate with the types of products being regulated.
    - Unlikely that oral products will be reviewed under the new mechanism due to DSHEA
    - Topical products (e.g., sunscreens) are ill-suited to NDA clearance mechanism – sold in a variety of sizes/formulations; NDA supplements for such changes are impractical given the nature of the products (established safe and effective marketing) and lack of marketing exclusivity.

- Proposed regulatory requirements overly burdensome. Several comments to the proposed rule expressed concern regarding lack of interim ("at risk") marketing upon determination of eligibility. At risk marketing has been permitted for U.S. products.
- (2) Timeliness of review.
- Agency response time on petitions has been extremely slow (some pending as long as 5-20 years).
  - Difficult to rationalize and has led frustrated industry to seek attention to these matters through other means (e.g., legislative).
  - Decision-making needs to take place within reasonable timeframes.
  - Agency has stated it has limited resources to devote to the review of OTC monograph products.
  - Third Party Review mechanism utilized in CDRH for review of 510(k) medical devices. Has been successful in expediting review time.
  - Proposal for third party review pilot program submitted to OTC Drug Division in 1998 by a coalition of European sunscreen ingredient manufacturers.
  - The proposal outlined the applicability of Third Party Review to OTC drug monograph process:
    - (1) Section 907 of FDCA (21 USC 397) provides authority for FDA to contract with outside experts in the review of petitions or other requests for review or classification of a product. Such authority may be used

whenever it is determined that use of a contract would improve the timeliness of the review, and particularly if the contract will improve the quality of the review.

- (2) Proposal recommended use of FDA accredited organizations to perform initial review;
- (3) Industry would pay for initial review;
- (4) Accredited organization makes recommendations to FDA re: eligibility (TEA application) and safety/efficacy determination using FDA criteria;

- A relatively simple mechanism to implement that has already been explored in the medical device area.
- Since 1998, we have yet to receive a response from the Agency regarding the proposal.

### **C. Closing Remarks (R. Pinco)**

- One small sign of progress is that FDA is in the process of dismantling old policy regarding foreign marketing.
- Is this a decision to treat the OTC Review as a long-term mechanism or is it designed for failure?
- Need a regulatory mechanism for OTC drugs that is viable. NDA mechanism is not appropriate. Need to address 3 categories of OTC products: (1) foreign-marketed products, (2) modifications to existing products, (3) Rx to OTC switches.
- Unless modified in accordance with industry comments, eligibility criteria outlined in Proposed Rule will not result in viable approach. Industry will become stagnant and may be forced to demand policy change through other avenues (e.g., legislation, litigation).

- Example: Natural products industry. FDA did not act to regulate as OTC drugs, and industry lobbied Congress for flexible approach was adopted with enactment of DSHEA. Note also that NDMA changed name to CHPA – Reflects the booming dietary supplement market.
- Major loser in this scenario is the public health – Public health suffers as a result of FDA inaction.
- Important not to establish OTC regulatory mechanisms that are unusable – It is important that the mechanism be commensurate with the products being regulated
  - Sassafras tea example – Must examine the big picture and not merely the individual components.
- The number of people attending this hearing demonstrates that the OTC Review is a critical part of healthcare, not a backwater approach where everything is done by OTC switches.